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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,152	06/21/2000	David J. Yang	UTXC:664	6919
7590	06/25/2004			
Teresa J Bowles 600 Congress Avenue Suite 2400 Austin, TX 78701				
			EXAMINER JONES, DAMERON LEVEST	
			ART UNIT 1616	PAPER NUMBER

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/599,152

Applicant(s)

YANG ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4,6-35,37-41 and 52-61 is/are pending in the application.
- 4a) Of the above claim(s) 56-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4,6,8-10,15,23,30-35 and 37-41 is/are rejected.
- 7) ☒ Claim(s) 7,11-14,16-22,24-29 and 52-55 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/8/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 4/8/04 wherein the claim status is as follows: claims 1, 5, 36, and 42-51 are canceled; claims 2, 7, 9, 20, 32, and 35 are amended; and claims 56-61 were added.

Note: Claims 2-4, 6-35, 37-41, and 52-61 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments filed 4/8/04 to the rejection of claims 2-4, 6, 8-10, 15, 20, 23, 30-35, and 37-41 made by the Examiner under 35 USC 112 have been fully considered and deemed persuasive-in-part for the reasons set forth below.

112 First Paragraph Rejections

The rejection of claims 2-4, 6, 8-10, 15, 23, 30, 31, 33-35, and 37-41 under 35 USC 112, first paragraph, because the specification while being enabling for methods of synthesizing a radiolabeled ethylenedicysteine (EC) complex wherein the tissue specific ligand is selected from (a) anticancer agents methotrexate, doxorubicin, tamoxifen, paclitaxel, topotecan, LHRH, mitomycin C, etoposide, tomudex, podophyllotoxin, mitoxantrone, camptothecin, colchicines, endostatin, fludarabin, and gemcitabine; (b) tumor markers PSA, ER, PR, CA-125, CA-199, CEA, AFP, interferon, BRCA1, HER-2/neu, cytoxan, p53, and endostatin; (c) folate receptor targeting agents folate, methotrexate, folic acid, and tomudex; (d) tumor apoptotic cell targeting ligands and tumor hypoxia targeting agents annexin V, nitroimidazole, mitomycin, colchicine, and metronidazole; (e) glutamate pentapeptide; (f) glucose mimics neomycin, kanamycin,

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entamycin, paromycin, amikacin, tobramycin, netilmicin, ribostamycin, sisomicin, micromicin, lividomycin, dibekacin, isepamicin, astromicin, glucosamine, and aminoglycoside; and (g) glucose, does not reasonably provide enablement for all tissue specific agents wherein the agents are anticancer agents, tumor markers, folate receptor targeting ligands, tumor apoptotic cell targeting ligands, tumor hypoxia targeting ligands, or agents that mimic glucose, is MAINTAINED for reasons of record in the office action mailed 9/29/03.

Applicant's arguments may be summarized as follows: (1) no factual basis has been set forth to rebut the teachings of the specification that undue experimentation is necessary to obtain a tissue specific ligand wherein the ligand is 'an anti-cancer agent', 'a tumor marker', 'a folate receptor targeting ligand', 'a tumor apoptotic cell targeting ligand', 'a tumor hypoxia targeting ligand', 'a tumor apoptotic cell targeting ligand', and 'an agent that mimics glucose', and so forth; (2) the art related to the claimed invention is well developed; and (3) the specification provides sufficient guidance to perform the invention.

All of Applicant's arguments set forth in the response filed 4/8/04 have been considered but not found persuasive. First, undue experimentation is necessary to determine what specific species are encompassed by the instant invention since the invention is directed to all species, known and unknown, which are encompassed by the terms above. Also, the terms are such that a person of ordinary skill in the art would be forced to engage in undue experimentation, with no assurance of success, because some species are encompassed by multiple categories. For example, Applicant's

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response to the 112, second paragraph, rejection of claim 32 and the term 'octreotide'. The Examiner's position is that art was cited against peptides. Applicant responded by saying that that term 'octreotide' was not removed from the claim because it may be an anti-cancer agent as set forth in Table 2, page 36, of the specification. Thus, while page 36, Table 2, disclose 'octreotide' as an anti-cancer agent, page 5, lines 8 and 11 disclose that a preferred tissue specific ligand is a peptide and page 6, lines 14-15, list 'octreotide' as a peptide. Hence, clarity of Applicant's claims is needed and undue experimentation is necessary to practice the invention. Also, while art related to EC may be known, art relating to all the tissue specific ligands is not since novelty of the invention is directed to the radiolabeling of the specific tissue ligands with EC, not EC itself. Thus, what the tissue specific ligands that are enabled by the instant invention are of concern. As a result, species which were not envisioned by Applicant are not properly enabled. In other words, the invention encompasses species in which Applicant had no knowledge what the species are and that they could be radiolabeled with EC. Furthermore, the claims as written may be considered as 'reach thru' claims since they aim to claim later discovered subject matter.

112 Second Paragraph Rejections

- I. The 112 rejections of claims 9 and 20 are WITHDRAWN for reasons of record in Applicant's response.
- II. The rejection of claims 2-4, 6, 8-10, 15, 23, 30, 31, 33-35, and 37-41 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point

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out and distinctly claim the subject matter which Applicant regards as the invention is MAINTAINED for reasons of record in the office action mailed 9/29/03 and those below.

Applicant asserts that the 112, second paragraph, rejections should be withdrawn based on the arguments presented above for the 112, first paragraph, rejection.

Applicant's arguments are not found persuasive and are maintained for the reasons set forth in response to the 112, first paragraph, rejections above.

III. The rejection of claim 32 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is MAINTAINED-IN-PART for reasons of record in the office action mailed 9/29/03 and those set forth below. Specifically, the rejection of the term 'octreotide'⁹ is MAINTAINED.

Applicant asserts that term 'octreotide' was not removed from the claim because it may be an anti-cancer agent as set forth in Table 2, page 36, of the specification.

While Applicant does disclose 'octreotide' on page 36, Table 2, as an anti-cancer agent, page 5, lines 8 and 11 disclose that a preferred tissue specific ligand is a peptide. Page 6, lines 14-15, list 'octreotide' as a peptide. Hence, we art was presented rendering peptides obvious, Applicant's argument is now that 'octreotide' is an anti-cancer agent; thus, no encompassed by a tissue specific peptide? Thus, Applicant's response supports the Examiner's position that based on the terms listed in the 112, first and second paragraph, rejections, one cannot readily determine what is encompassed by the terms of the instant invention. As a result, how is one to

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determine exactly what the terms encompass if when prior art is cited against terms that are encompassed by multiple categories, Applicant's position becomes that the term should remain because it falls within another category? Hence, the rejection is being maintained on the basis that 'octreotide' is a peptide that is listed as a peptide in the specification and art has previously been cited against peptides.

ELECTION BY ORIGINAL PRESENTATION

3. Newly submitted claims 56-61 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: in particular, the claims are broader than the claims previously examined. For example, independent claims 56, 58, and 59 read on any and all tissue specific ligands.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 56-61 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

CLAIM OBJECTIONS

4. Claims 7, 11-14, 16-22, 24-29, and 52-55 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Note: The claims are distinguished over the prior art of record for reasons of record in the office action mailed 9/29/03.

COMMENTS/NOTES

5. It is duly noted that Applicant has submitted a 14-page information disclosure statement having appropriately 185 references. Applicant is reminded of their obligation to call the most pertinent prior art to the attention of the US Patent and Trademark Office in a proper fashion since burying one reference in one hundred other references would not be improper.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617.

The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


D. L. Jones
Primary Examiner
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June 24, 2004